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09/866,261	05/25/2001	Thuy Diem Pham	TPB-001D1	8078

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The H.T. Than Law Group  
1010 Wisconsin Ave. NW  
Suite 560  
Washington, DC 20007

EXAMINER
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KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/866,261

Applicant(s)

PHAM, THUY DIEM

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,6,7,13,15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,13,15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/25/01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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## **DETAILED ACTION**

### ***Preliminary Remark***

Applicants' Preliminary Amendment received on May 25, 2001, canceling claims 3-5, 8-12, 14, and 16; and adding claim 17 is acknowledged.

Claims 1, 2, 6, 7, 13, 15, and 17 are pending and are under prosecution therefore.

### ***Priority***

MPEP 201.11(B) describes that the status of all prior-filed non-provisional applications must be updated in the first line of the specification. The preliminary amendment received on May 25, 2001, amends the instant specification, referring to parent application 09/159,325, but its status is not updated.

Correction is required.

Applicants are advised that the parent application 60/061,287 does not disclose SEQ ID Numbers 7 and 8 of the instant application and hence, the priority to this application for claims 13, 15, and 17 is **denied**.

The effective filing date for the above claims, therefore, has been determined to be September 23, 1998.

### ***Information Disclosure Statement***

The IDS received on May 25, 2001 is acknowledged.

A signed copy of its PTO-1449 is attached hereto.

### ***Drawings***

The drawings received on May 25, 2001 are acceptable.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7, 13, 15, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 7, 13, 15, and 17 are indefinite because the preamble of the method recites that said method is for determining the, “subgroup specificity of nucleic acid of naturally occurring avian leucosis/sarcoma virus,” as it is unclear what this phrase is intending to achieve.

For the purpose of prosecution, the phrase is interpreted to mean distinguishing between the different subgroups of avian leucosis/sarcoma virus.

Claims 13, 15, and 17 are rejected because it is unclear what metes and bounds are embraced by an oligonucleotide sequence that is at least 95% identical to (embodiment c) an oligonucleotide which hybridizes under stringent hybridization conditions to a [sic] oligonucleotide defined by (a) or (b). As the oligonucleotide (first oligonucleotide) that hybridizes under stringent hybridization condition to an oligonucleotide of SEQ ID NO: 7 or 8 (as defined in (a)); or a nucleotide sequence encoding any gp<sup>env</sup> 85 protein must have some degree of identity to oligonucleotide of (a) or the nucleotide sequence of (b), it is unclear what an oligonucleotide that is 95% homologous to the first oligonucleotide would embrace.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description Rejection.

Claims 13, 15, and 17 are drawn to a method of detecting the nucleic acid of avian leucosis/sarcoma and a method of determining the subgroup specificity of the nucleic acid of avian leucosis/sarcoma, involving an oligonucleotide having at least 95% homology to a nucleotide sequence encoding any gp<sup>env</sup>85 protein.

The claims embrace a genus of nucleotide sequences encoding gp<sup>env</sup>85 protein from any species, wherein the instant specification has not disclosed a representative number of species embraced by the claims.

The written description requirement ensures that, "an applicant invented the subject matter which is claimed. Further, the written description requirement for a claimed genus may be satisfied *through a* sufficient description of *a representative number of species* by 1) reduction to practice; 2) reduction to drawing; or 3) disclosure of relevant identifying characteristics (*i.e.*, structure of other physical and/or chemical properties, functional characteristics *coupled* with a known or disclosed correlation between function and structure) (MPEP 2163 at II(A)(3)(a)(ii)).

***Reduction to Practice***

The instant specification identifies primer sequences which flank various regions along a nucleotide sequence encoding gp<sup>env</sup>85 protein, wherein the instant specification disclose that the nucleotide sequence is identified from Prague C strain of RSV (page 28).

While the instant specification admits that nucleotide sequence encoding gp<sup>env</sup>85 contains “hypervariable region,” the instant claims nevertheless embrace a method that employs an oligonucleotide that is 95% homologous to a host of nucleotide sequences which comprise hypervariable region that encode gp<sup>env</sup> protein of any organism and species.

The instant specification simply does not have written description for a method which involves the use of nucleotide sequences that encode any gp<sup>env</sup> 85 protein.

It is known that gp<sup>env</sup> protein can be found in a plurality of species – HPRS-103 (subgroup J) avian leucosis virus, EBV, FeLV (feline leukemia virus), different strains within each of the different subgroups of ALV, such as strains VR-334 and 335 subgroup A; VR 657 and 658 for subgroup B, etc.

The fact that different strains are present within each of the subgroup of ALV is communicated by Hauptli et al. (Journal of Virological Methods, 1997, vol. 66, pages 71-81), wherein the artisans express:

“Three sets of degenerate oligonucleotide primers were synthesized by Microsynth, Switzerland. Primers were designed to detect ALV subgroups A to E. Regions of gp85 env gene showing the highest degree of conservation between different ALV strains were selected.” (page 73, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph)

The instant specification simply does not have the nucleotide sequences encoding, among may others, the gp<sup>env</sup> 85 protein of the at least the above species.

### ***Reduction to Drawing***

The instant specification discloses primers PA1 and PA2 which flanks the hypervariable region of nucleotide sequence encoding gp<sup>env</sup> 85 protein, from subgroup A; PA10 and PA20 which flanks a region within the hypervariable region; PB1 and PB2, which flanks the hypervariable region of nucleotide sequence encoding gp<sup>env</sup> 85 protein from subgroup B; PC1 and PC2 which flanks the hypervariable region of the nucleotide sequence encoding gp<sup>env</sup> 85 protein from subgroup C; PD1 and PD2 which flanks the hypervariable region of the nucleotide sequence encoding gp<sup>env</sup> 85 protein from subgroup D; and PE1 and PE2 which flanks the hypervariable region of the nucleotide sequence encoding gp<sup>env</sup> 85 protein from subgroup E. All subgroups were from the same strain – Prague C strain of RSV (page 13, lines 15-16; page 28; Table 1).

No other primer sets or sequences that correspond to different species of ALV are disclosed.

### ***Disclosure of Relevant Identifying Characteristics***

While one could argue that a skilled artisan would be able to identify the “representative number of species” which encodes gp<sup>env</sup> 85 protein through routine experimentation, as stated in *University of California v. Eli Lilly and Co.* at page 1404:

An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, ***"an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself."*** *Id.* at 1170, 25 USPQ2d at 1606.

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Therefore, for the foregoing reasons, the genus embraced by the claims is not sufficiently described by the number of species disclosed in the specification, and therefore, the specification lacks written description of the claims.

Claims 6, 7, 15, and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of determining the subgroup specificity of nucleic acid of naturally occurring avian leucosis/sarcoma virus, wherein the subgroup are subgroups A-E, does not reasonably provide enablement for a method of determining the subgroup of specificity of nucleic acid of naturally occurring avian leucosis/sarcoma virus, wherein the subgroup is J. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

MPEP 2164.01, in discussing the test of enablement, states:

“Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention.”

It is the position of the Office that at the time the application was filed, Applicants did not enable a skilled artisan to determine subgroup J of avian leucosis/sarcoma virus for the following reasons.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in *In Re Wands* (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir.



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1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

(A) Quantity of Experimentation: The instant specification identifies a universal primer set (PU1 and PU2) that flank the hypervariable region of a nucleotide sequence encoding gp<sup>env</sup> 85 protein in avian leucosis/sarcoma virus, allowing the amplification of gp<sup>env</sup> 85 encoding region from all subgroups A, B, C, D, and E (page 32, lines 14-16). The instant specification then describes primer set(s) that are specific for identifying a specific subgroup of avian leucosis/sarcoma virus, such as PA1 and PA2; PB1 and PB2; PC1 and PC2; PD1 and PD2; and PE1 and PE2 (page 33, lines 1-4). Nowhere in the specification does it contain any guidance pertaining to determining subgroup J of avian leucosis/sarcoma virus, requiring of a skilled artisan an undue amount experimentation.

(B) Absence of Guidance: The specification teaches that recent molecular characterization of a newly isolated leucosis virus from meat-type chickens showed that subgroup J ALSV contains gene sequences homologous to both exogenous and endogenous viral elements. (page 3, lines 14-18). The specification, however, does not give any guidance for a skilled artisan to distinguish subgroup J from subgroups A-E.

(C) Absence of Examples: The instant specification gives examples pertaining to primers that are employed in specifically amplifying a region from the nucleotide sequence encoding gp<sup>env</sup> 85 protein of avian leucosis/sarcoma virus subgroups A-E. The instant specification, however, fails to give any example pertaining to primers which could be employed in

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specifically amplifying a region from the nucleotide sequence encoding gp<sup>env</sup> 85 protein of avian leucosis/sarcoma virus subgroup J.

(D) Nature of the Invention: The nature of the invention relates to a method of identifying a particular subgroup of an avian leucosis/sarcoma virus via RT-PCR involving primers that are specific for said particular subgroup.

(E) State of prior art: Hauptli et al. disclose that recently a new exogenous subgroup J had been identified (page 72, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph). The artisans also disclose that the strain HPRS-103, representing subgroup J, “differed considerably from the env genes of other ALV subgroups it was not included in” their study (page 73, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph)

(F) Relative Skill level: The skilled level of the artisan is considered to be high.

(G) Unpredictability of art: Absent disclosure of nucleotide sequence encoding gp<sup>env</sup> 85 protein of subgroup J, design of primer sets that are specifically distinguish subgroup J from other subgroups remains unpredictable, requiring empirical determination.

(H) Breadth of claims: The breadth of claims embrace a method which distinguishes between subgroups A-E and J of avian leucosis/sarcoma virus via RT-PCR, requiring primers that are specific for each of the avian leucosis/sarcoma virus subgroups.

As the nature of detecting a particular species via amplification process is unpredictable, guidance on the structure of the species as well as empirical determination of whether a particular oligonucleotide (i.e., primers/probes) would be effective in identifying that particular species (i.e., do not cross-hybridize) is necessary. This fact is clearly communicated by Hauptli et al., wherein the artisans state:

“On the basis of known gene sequences three sets of degenerate primers were selected. This was achieved by alignment of documented genomic gp85 env gene sequences

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available. After optimization of reaction conditions, by varying different parameters, such as pH, MgCl<sub>2</sub>, KCl, temperature profile of cycling all strains of AVL including subgroups A to E were amplified successfully using the three different sets of primers.” (page 75, 3.1 PCR amplification).

“The specificity of the ALV RT-PCR was demonstrated using several unrelated avian RNA and DNA virus including reovirus, infectious bronchitis virus, infectious bursal disease virus, encephalomyelitis virus, turkey herpes virus and Marek’s disease virus. Using primer pair ALVgp85U3/L3, which amplified a 466 bp ALV fragment, no specific band was observed within 18 unrelated avian viral nucleic acid templates.” (page 77, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph)

Therefore, one of ordinary skill in the art, based on the instant specification and prior art, while being able to distinguish between subgroups A-E, would not reasonably be able to practice the invention fully in commensurate with scope of the claims without undue experimentation because the specification would not enable a skilled artisans to reasonably distinguish between subgroup J of the avian leucosis/sarcoma virus from subgroups A-E.

Amending the claims to become drawn to a method of determining the subgroup specificity of nucleic acid of naturally occurring avian leucosis/sarcoma virus, wherein the subgroups are A-E would overcome this rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Hauptli et al. (Journal of Virological Methods, 1997, vol. 66, pages 71-81; IDS ref# AD) in view

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of Spencer et al. (Avian Disease, 1977, vol. 21, no. 3) and Bohinski et al. (U.S. Patent No. 5,976,873, issued November 2, 1999, May 17, 1995).

Hauptli et al. disclose a method of detecting the presence of avian leucosis virus, said method comprising the steps of:

- (a) isolating viral RNA from allantoic fluids of SPF eggs;
- (b) RT-PCR using primer pairs ALVgp85U3/L3;
- (c) detecting the presence of the virus (page 78).

The RT-PCR primers are derived from nucleotide sequence encoding gp<sup>env</sup>85 protein (page 75, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph), meeting limitation of, “an oligonucleotide having a sequence having at least 95% identical to...a nucleotide sequence encoding the gp<sup>env</sup> 85 protein.”

Hauptli et al., in isolation of RNA, employ the reagent, Trizol<sup>TM</sup> LS (page 73, 2<sup>nd</sup> column, bottom paragraph) rather than the claimed  $\beta$ -mercaptoethanol.

Hauptli do not extract viral RNA from egg albumen.

Spencer et al. disclose a well known-knowledge of leukosis virus being present in chicken eggs, their albumen, embryos, chicks, and hens (Abstract).

The use of  $\beta$ -mercaptoethanol in RNA isolation has been well-established in the art of nucleic acid extraction as evidenced by Bohinski et al. (column 50, lines 39-44).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hauptli et al. with the teachings of Bohinski et al. to extract viral RNA from samples using well-known equivalent reagent (from Trizol to mercaptoethanol). One of ordinary skill in the art at the time the invention was made would also

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have been motivated to detect viral RNA from sources wherein its residence had been well-characterized, as evidenced by Spencer et al.

MPEP, at 2144.06, in discussing substitution of equivalents for the same purpose, states:

“In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art...”

RNA extraction via use  $\beta$ -mercaptoethanol has been practiced in the art for quite some time, as evidenced by Bohinski et al., and therefore, the equivalency of employing  $\beta$ -mercaptoethanol rather than Trizol, for the same purpose – RNA extraction – has been fully established, rendering claims 1, 2, and 13 obvious..

Applicants are advised that the claim 13, while containing an embodiment to employing an oligonucleotide at least 95% identical to SEQ ID Numbers 7 or 8, also contains embodiment drawn to employing an oligonucleotide at least 95% identical to any nucleotide sequence encoding gp<sup>env</sup>85 protein. As the primers employed by Hauptli et al. are designed to detect ALV subgroups A to E – i.e., derived from regions of gp<sup>env</sup> 85 gene (page 73, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph) – said primers would necessarily contain at least 95% identity to a nucleotide sequence encoding gp<sup>env</sup> 85 protein.

Therefore, the invention as claimed is *prima face* obvious over the cited references.

Claims 6, 7, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauptli et al. (Journal of Virological Methods, 1997, vol. 66, pages 71-81; IDS ref# AD), Spencer et al. (Avian Disease, 1977, vol. 21, no. 3) and Bohinski et al. (U.S. Patent No.

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5,976,873, issued November 2, 1999, May 17, 1995) in view of Bova et al. (Journal of Virology, 1988, vol. 62, no. 1, pages 75-83; IDS ref # AB).

Hauptli et al. disclose a method of detecting the presence of avian leucosis virus, said method comprising the steps of:

- (a) isolating viral RNA from allantoic fluids of SPF eggs;
- (b) RT-PCR using primer pairs ALVgp85U3/L3;
- (c) detecting the presence of the virus (page 78).

The RT-PCR primers are derived from nucleotide sequence encoding gp<sup>env</sup>85 protein (page 75, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph), meeting limitation of, “an oligonucleotide having a sequence having at least 95% identical to...a nucleotide sequence encoding the gp<sup>env</sup> 85 protein.”

Hauptli et al. also distinguish each of the subgroups A-E via determining their restriction enzyme digestion pattern on an electrophoretic gel (Table 2).

Hauptli et al. do not employ DNA sequencing for this distinction.

Hauptli et al., in isolation of RNA, employ the reagent, Trizol<sup>TM</sup> LS (page 73, 2<sup>nd</sup> column, bottom paragraph) rather than the claimed  $\beta$ -mercaptoethanol.

Hauptli do not extract viral RNA from egg albumen.

Bova et al. disclose a method of distinguishing between different avian leucosis/sarcoma subgroup D and subgroup A via well known nucleic acid sequencing method such as chemical cleavage and dideoxy chain termination method (page 76, 2<sup>nd</sup> column, 4<sup>th</sup> paragraph). The artisans disclose that a complete sequence was determined on both strands of DNA.

Spencer et al. disclose a well known-knowledge of leukosis virus being present in chicken eggs, their albumen, embryos, chicks, and hens (Abstract).

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The use of  $\beta$ -mercaptoethanol in RNA isolation has been well-established in the art of nucleic acid extraction as evidenced by Bohinski et al. (column 50, lines 39-44).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the subgroup distinction step of Hauptli et al. with the nucleic acid sequencing method of Bova et al. for the following reasons.

MPEP, at 2143.02, states that the prior art can be modified or combined to reject claims as obvious as long as there is a reasonable expectation of success.

It is clear that Hauptli et al. amplify the region of nucleic acid sequences encoding gp<sup>env</sup> 85 protein of avian leucosis/sarcoma virus subgroups A-E. The amplified products, which represent subgroups A-E, are disclosed as having the expected size of 371 base pairs (page 75, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph). Further, the amplified products are digested producing different restriction patterns (Table 2), evidencing the presence of different sequences between the subgroups.

Therefore, one of ordinary skill in the art would have had a reasonable expectation of success at sequencing the amplified product of Hauptli et al. in distinguishing between the different avian leucosis/sarcoma virus subgroups, as nucleic acid sequencing method had been well-established in the art and commonly employed in comparing and distinguishing nucleic acid sequences of different species, as evidenced by Bova et al.

With regard to distinguishing between endogenous and exogenous retrovirus, Hauptli et al. disclose that subgroup E is endogenous and subgroups A-D are exogenous (page 72, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph). Therefore, distinguishing between each avian subgroups would

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necessarily allow one of ordinary skill in the art to distinguish between endogenous and exogenous retrovirus.

Additionally, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hauptli et al. with the teachings of Bohinski et al. to extract viral RNA from samples using well-known equivalent reagent (from Trizol to mercaptoethanol). One of ordinary skill in the art at the time the invention was made would also have been motivated to detect viral RNA from sources wherein its residence had been well-characterized, as evidenced by Spencer et al.

MPEP, at 2144.06, in discussing substitution of equivalents for the same purpose, states:

“In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art...”

RNA extraction via use  $\beta$ -mercaptoethanol has been practiced in the art for quite some time, as evidenced by Bohinski et al., and therefore, the equivalency of employing  $\beta$ -mercaptoethanol rather than Trizol, for the same purpose – RNA extraction – has been fully established.

Applicants are advised that the claims 13, 15, and 17, while containing an embodiment to employing an oligonucleotide at least 95% identical to SEQ ID Numbers 7 and 8, also contains embodiment drawn to employing an oligonucleotide at least 95% identical to any nucleotide sequence encoding gp<sup>env</sup>85 protein. As the primers employed by Hauptli et al. are designed to detect ALV subgroups A to E – i.e., derived from regions of gp<sup>env</sup> 85 gene (page 73, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph) – said primers would necessarily contain at least 95% identity to a nucleotide sequence encoding gp<sup>env</sup> 85 protein.



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Therefore, the invention as claimed is *prima facie* obvious over the cited references.

### ***Conclusion***

No claims are allowed.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a

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general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim

Patent Examiner

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3/12/05

**YOUNG J. KIM  
PATENT EXAMINER**

yjk